REMARKS

Upon entry of the amendments, claims 38-68 are pending in the application. Claims 38 and 67 have been amended, and claims 61-65 have been withdrawn from consideration. Basis for the amendments can be found on page 41, lines 4-8, of the current specification. Therefore, the amendments do not introduce any new matter within the meaning of 35 U.S.C. §132. Accordingly, entry of the amendments is respectfully requested.

35 U.S.C. §103(a) REJECTION

Claims 38-60, 66, 67 and 68 stand rejected as being unpatentable over U.S. Patent No. 4,863,743 (Hsiao) in view of U.S. Patent No. 5,567,439 (Myers) and U.S. Patent No. 4,764,375 (Paradissis). In support of the rejection, the Examiner states:

> The instant claims are silent as to the Flavoring agent, animal, particles, and extended release coating. Hsiao can be construed as meeting them, with the sugar, used in coated prior art tablets (col. 7, last paragraph, top and col. 8), if flavor is deemed a parameter of concern. In all other respects, Hsiao provides coated Kcl (Example 1) granules, with microcrystalline cellulose and crospovidone, PEG, as tablets, Example 2, addes magnesium stearate; similar to applicants Na-stearyl fumerate of Example 1; the tablets are the instant formulations of 20m Eq of Kcl. However 68%-86% Kcl is shwon (column 7). Disintegration occurs within 5 minutes (column 5, lines 19-24) with sustained release leading to 90% Kcl released after 6 hours (Tables I, II).
> The components providing for the dispersing and releases periods as instantly claimed are thus Hsaio.
>
> Administration as a liquid was seen as placing in water, or no awueous food, which is then administered to those having swallowing difficulties (col. 5) line 65- line 7 col. 6). Stiring and Mixing if desired, is known - it was used in preparation (Example 2) thus would be within the purview of one to perform, if the desired dissolution period shorter than produced by simply placing in water. This is the instant invention, absent a clear showing of coloring and flavorant. Paradissis is evidence it was well known at the time of the instant invention, to add colorants and flavorants even to taste-masked coated actives (col. 2), including Kcl (claim 7), for particle dispersion in liquids. Further, multi substance preparations are also known (col. 2, lines 35, 36). Myers discloses examples of Flavorants (col. 9 top through line 7, col. 10 and colorants (col. 10, lines 28-33) useful in drug tablet (col. 7, lines 47-49) compositions.
>
> It would have been obvious to a person of ordinary skill in the art at the time invention was made, desiring to utilize Hsiao's Kcl tablet in a form to provide enhanced palatability, disperability and sustained release, as taught by paradissis and exemplified by Myers.

Applicants respectfully traverse this rejection. The claims as currently amended further define the present invention and more clearly explain its superior qualities over the compositions contained in the cited references.

The present invention is drawn towards a method of patient compliance by administering the non-effervescent flavored suspensions of the present invention. The method utilizes suspensions which are flavored, tastemasked and have a controlled release profile of about 2 to about 48 hours. As such, the present methods may have improved palatability to a patient and reduce the unpleasantness associated with administration. Further the present methods may reduce the number of doses required due to the controlled release profile.

Hsiao teaches tablets which are sweetened. Flavorings and tastemasking are not taught. Further, Hsiao teaches, in Table I, that the controlled release is such that at least 91% of the active agent is released within 6 hours. As such, the tablets of Hsiao would result in a tablet, which was not as palatable as the one utilized in the present methods and which releases the active over a shorter period of time.

The secondary references do not remedy these deficiencies. Myers teaches tastemasking via an effervescent agent, which is outside the scope of the present invention. The present invention specifically avoids effervescent technologies. As stated in the present

specification on page 36, lines 12-14, effervescence is viewed as having a negative impact upon patient compliance. Paradissis likewise fails. Paradissis is concerned only with the complete tastemasking of active agents. Paradissis is not concerned with the overall design of a method to enhance patient compliance but rather a specific form of tastemasking of hydrophillic active agents.

In contrast, the present invention is directed to a method which has identified those elements critical to improving patient compliance. The system must be noneffervescent, have a delayed release profile, and must be both flavored and tastemasked. This superiority of this method is not rendered obvious by the teachings of the references cited by the Examiner.

CONCLUSION

If the Examiner has any questions or wishes to discuss this matter, he is welcomed to contact the undersigned attorney.

Respectfully submitted,

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